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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,432 04/10/2001		04/10/2001	Karen A. Ketchum	CL001013-CIP	8734
25748	7590	06/18/2002			
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45 WEST GU C2-4#20		NTGOMERY, VIC VE	SEHARASEYON, JEGATHEESAN		
ROCKVILLE	E, MD 2	0850	ART UNIT	PAPER NUMBER	
				1647	
				DATE MAILED: 06/18/2002	

Please find below and/or attached an Office communication concerning this application or proceeding.

1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413) Paper No(s)		Application No.	Applicant(s)					
Jegatheesan Seharaseyon	Office Action 0	09/829,432	KETCHUM ET AL.					
The MALING DATE of this communication appears on the cover sheet with the correspondence address — Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE £ MONTH(S) FROM THE MALINIO DATE OF THIS COMMUNICATION.  THE MALINIO DATE OF THIS COMMUNICATION.  The MALINIO DATE OF THIS COMMUNICATION.  If the period to reply separate similing date of its communication.  If the period to reply separate similing date of its communication.  If the period to reply separate shows, the maximum stanking printed villagely and vill explose SIG (MONTHS from the mailing date of this communication.  If the period to reply separate shows, the maximum stanking printed villagely and villagely SIG (MONTHS from the mailing date of this communication.  If the period to reply separate shows, the maximum stanking printed villagely and villagely SIG (MONTHS from the mailing date of this communication.  If the period to reply separate shows, the maximum stanking printed villagely and villagely SIG (MONTHS from the mailing date of this communication.  A prophy received by the Office later than these mosths after the mailing date of this communication.  A prophy received by the Office later than these mosths after the mailing date of this communication.  A prophy received by the Office later than these mosths after the mailing date of this communication.  A prophy received by the Office later than these mosths after the mailing date of this communication.  A prophy received by the Office later than the mailing date of this communication.  A prophy received by the Office later than the mailing date of this communication.  A prophy received by the Called by the prophy received than the mailing date of this communication.  A prophy received by the prophy received by the Examiner.  A policition of the above claim(s) in the application is non-final.  A policition of the prophy received the prophy received the prophy received by the Examiner.  A policition of the prophy received the prophy received by the Examiner.  A policition of	Oπice Action Summary	Examiner	Art Unit					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THEM MALING DATE OF THIS COMMUNICATION.  - Extensions of form may be available under the promision of 37 CFR 1 134(a). In no overert, however, may a reply be timely filed after Sk (6) MONTHS from the making date of this communication of 37 CFR 1 134(a). In no overert, however, may a reply be timely filed after filed to provide them to the state of this communication of 37 CFR 1 134(a). In no overert, however, may a reply be timely filed after them the making date of this communication.  - Evaluate to reply within the set or extended period for reply, with by stand with apply and with source 30 (c) MONTHS from the making date of this communication on the set or extended period for reply, with by stand with apply and with source 30 (c) MONTHS from the making date of this communication, even if timely filed, may reduce any seamed palent term adjustment. See 37 CFR 1.74(b).  - Any reply received by the Office of the fine from anomalising date of this communication, even if timely filed, may reduce any seamed plant term adjustment. See 37 CFR 1.74(b).  - Any reply received by the State of the State of the State of the Communication of Communication.  - Applicant term adjustment. See 37 CFR 1.74(b).  - This action is FINAL.  - Applicant and accordance with the practice under Exparte Quayle, 1935 C.D. 11, 453 O.G. 213.  - Disposition of Claims  - Application is Jarae allowed.  - Claim(s) is/are rejected.  - Claim(s) is/are rejected.  - Claim(s) is/are allowed.  - Claim(s) is/are objected to.  - Si) Claim(s) is/are objected to.  - Application Papers  - Priority and a standard and standar								
THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of dism may be audisted where the provisions of 37 CPR 1.136(a). In no event, however, may a reply be timely filled after SN (6) MONTHS from the mailing date of this communication.  - Into pariod for reply is specified above, the maximus of 37 CPR 1.136(a).  - Into pariod for reply is specified above, the maximus authory peck of the good and the state of the communication.  - Fisher to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (82 U.S.C. § 133).  - Any reply revised by the Ottoe uniter than there amount after the mailing date of this communication, even if timely filled, may reduce any  - Status  1)	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
2a) This action is FINAL. 2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 1-23 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) is/are elected.  7) Claim(s) is/are objected to.  8) Claim(s) 1-23 are subject to restriction and/or election requirement.  Application Papers  9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  11) □ The proposed drawing correction filed on is: a) □ approved by □ disapproved by the Examiner.  If approved, corrected drawings are required in reply to this Office action.  12) □ The oath or declaration is objected to by the Examiner.  Priority under 35 U.S.C. §§ 119 and 120  13) □ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) □ All b) □ Some * c) □ None of:  1. □ Certified copies of the priority documents have been received.  2. □ Certified copies of the priority documents have been received in Application No  3. □ Copies of the certified copies of the priority documents have been received in Application No  3. □ Copies of the certified copies of the priority documents have been received in Application No  3. □ Copies of the certified copies of the priority documents have been received in Application No  3. □ Copies of the certified copies of the priority documents have been received in Application for the International Bureau (PCT Rule 17.2(a)).  *See the attached detailed Office action for a list of the certified copies not received.  14) □ Acknowledgment is made of a claim for	THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) ○ Claim(s) 1-23 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) ○ Claim(s) is/are allowed.  6) ○ Claim(s) is/are allowed.  7) ○ Claim(s) is/are objected to.  8) ○ Claim(s) 1-23 are subject to restriction and/or election requirement.  Application Papers  9) ○ The specification is objected to by the Examiner.  10) ○ The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  11) ○ The proposed drawing correction filed on is: a) □ approved b) □ disapproved by the Examiner.  If approved, corrected drawings are required in reply to this Office action.  12) □ The oath or declaration is objected to by the Examiner.  Priority under 35 U.S.C. §§ 119 and 120  13) □ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) □ All b) □ Some* c) □ None of:  1. □ Certified copies of the priority documents have been received.  2. □ Certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailled Office action for a list of the certified copies not received.  14) □ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  a) □ The translation of the foreign language provisional application has been received.  15) □ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  Notice of Drattsperson's Patent Drawing Review (PTO-948)  5) □ Notice of Informal Patent Application (PTO-152)	1) Responsive to communication(s) filed on <u>06 Ja</u>	<u>une 2001</u> .						
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	1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal P	(PTO-413) Paper No(s) atent Application (PTO-152)					

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## **DETAILED ACTION**

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 4, 5, 8-11, 22 and 23 are drawn to a nucleic acid encoding a polypeptide, a vector and a host cell, classified in class 536, subclass 23.5.
  - II. Claims 1, 2, 20 and 21 are drawn to a protein, classified in class 530, subclass 350.
  - III. Claim 3 is drawn to an antibody, classified in class 530, subclass 387.1.
  - IV. Claim 6 is drawn to a gene chip comprising nucleic acid molecule classified in class 435, subclass 4.
  - V. Claim 7 is drawn to transgenic non-human animal classified in class 800, subclass 13.
  - VI. Claim 12 is drawn to a method of detecting the presence of the polypeptide, classified in class 435, subclass 7.1.
  - VII. Claim 13 is drawn to a method of detecting the presence of the nucleic acid, classified in class 435, subclass 6.
  - VIII. Claims 14, 15 and 19 are drawn to a method for identifying a modulator of the peptide, classified in class 435, subclass 7.1.
  - IX. Claim 16 is drawn to a method for identifying an agent that binds to polypeptides, classified in class 435, subclass 7.1.

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X. Claims 17 is drawn to a pharmaceutical composition, classified in class 514, subclass 2.

XI. Claim 18 is drawn to a method of treatment, classified in class 424, subclass 184.1.

The inventions are distinct, each from the other, for the following reasons:

Inventions I, II, and III are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The polynucleotide of invention I can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The polypeptide of invention II can be used as a probe or used therapeutically or diagnostically, e.g. in screening. The antibody of invention III can be used to obtain the polynucleotide of Group I, and can also be used in diagnostics, e.g. as a probe in immunoassays. In addition, the searches are not coextensive for these products.

Inventions I and (IV, V and VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention I can be used in gene therapy or in production of the recombinant protein.

Inventions I and (III, VI, VIII-XI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

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modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions II and (III, VI and VIII-XI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention II can be used in assays for the identification of aganoist and antaganoist of the polypeptide.

Inventions II and (IV, V and VII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions VI-XI are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

In addition, the searches are not coextensive for these inventions. Because these inventions are distinct for the reasons given above and have acquired a separate status

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in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

- 2. The claims of Groups I -II are drawn to multiple nucleic acid sequences (SEQ ID NO: 1-3). Each of the different nucleic acid sequences are independent and distinct because no common structural or functional properties are shared. Accordingly, these sequences are each subject to restriction under 35 U.S.C. § 121. Regardless of the Group elected, Applicant is additionally required to elect a single nucleic acid sequence, which if determined to be patentable, would also be patentably distinct from the other nucleic acid sequences. This requirement is made under 1192 O.G.68 Notice (November 19, 1996), as examination of more than one sequence in one application would result in an undue burden on the PTO.
- 3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS June 13, 2002

JEFFREY STUCKER
PRIMARY FXAMINER